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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,468	07/02/2003	Jingwu Z. Zang	057186.000003	5234

7590 03/09/2006

Attention: J. Wendy Davis, Ph.D.
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EXAMINER

JUEDES, AMY E

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/612,468	ZANG ET AL.	
	Examiner	Art Unit	
	Amy E. Juedes, Ph.D.	1644	

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 July 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-44 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

Art Unit: 1644

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

1. Claims 1, 2, and 5-6, drawn to an isolated DNA fragment and a vaccine comprising SEQ ID NO: 1; classified in Class 536, subclass 23.1.
2. Claims 3-6, drawn to an isolated DNA fragment and a vaccine comprising SEQ ID NO: 2; classified in Class 536, subclass 23.5.
3. Claims 7-8, 13-14, and 42-44, drawn to an isolated peptide derived from a BV14 TCR, or an isolated peptide comprising SEQ ID NO: 3 or SLS, and pharmaceutical compositions thereof; classified in Class 530, subclass 329.
4. Claims 10-11, 13-14, and 42-44, drawn to an isolated peptide derived from a BV16 TCR, or an isolated peptide comprising SEQ ID NO: 4, SQD, SLL, or SEQ ID NO: 5, and pharmaceutical compositions thereof; classified in Class 530, subclass 330.
5. Claim 9, drawn to an antibody specific for a BV14 TCR peptide; classified in Class 530, subclass 387.1.
6. Claim 12, drawn to an antibody specific for a BV16 TCR peptide; classified in Class 530, subclass 387.9.
7. Claims 15-16, drawn to a method for detecting rheumatoid arthritis by measuring the expression level of a BV14 TCR in a subject and a normal individual; classified in Class 536, subclass 24.3.
8. Claims 15-18, drawn to a method for detecting rheumatoid arthritis by measuring the expression level of a BV16 TCR in a subject and a normal individual; classified in Class 435, subclass 325.
9. Claims 19-20, drawn to a method for detecting rheumatoid arthritis by generating a probe complementary to SEQ ID NO: 1 and mixing the probe with a tissue sample; classified in Class 435, subclass 1.1.

Art Unit: 1644

10. Claims 19-20, drawn to a method for detecting rheumatoid arthritis by generating a probe complementary to SEQ ID NO: 2 and mixing the probe with a tissue sample; classified in Class 536, subclass 24.3.

11. Claims 21-22, drawn to a method for detecting rheumatoid arthritis by generating an antibody specific for a peptide consisting of SEQ ID NO: 3 or SLS, and mixing said antibody with a tissue sample; classified in class 530, subclass 388.75.

12. Claims 21-22, drawn to a method for detecting rheumatoid arthritis by generating an antibody specific for a peptide consisting of SEQ ID NO: 4, SQD, SLL, or SEQ ID NO: 5, and mixing said antibody with a tissue sample; classified in Class 530, subclass 388.7.

13. Claim 23, drawn to a method for treating rheumatoid arthritis comprising administering a peptide comprising SEQ ID NO: 3 or SLS; classified in Class 514, subclass 16.

14. Claim 23, drawn to a method for treating rheumatoid arthritis comprising administering a peptide comprising SEQ ID NO: 4, SQD, SLL, or SEQ ID NO. 5; classified in Class 514, subclass 17.

15. Claim 24, drawn to a method for treating rheumatoid arthritis comprising administering an antibody directed against a peptide having an amino acid sequence of SEQ ID NO: 3 or SLS; classified in Class 424, subclass 130.4.

16. Claim 24, drawn to a method for treating rheumatoid arthritis comprising administering an antibody directed against a peptide having an amino acid sequence of SEQ ID NO: 4, SQD, SLL, or SEQ ID NO: 5; classified in Class 424, subclass 139.1.

17. Claims 25-33, drawn to a method for treating rheumatoid arthritis comprising administering a nucleic acid encoding a TCR VB16 peptide; classified in Class 514, subclass 44.

18. Claims 34-41, drawn to a method for treating rheumatoid arthritis comprising administering a nucleic acid encoding a TCR VB14 peptide; classified in Class 514, subclass 44.

Art Unit: 1644

2. Groups 1-6 are different products. Nucleic acids (groups 1-2), polypeptides (groups 3-4), and antibodies to the polypeptides (groups 5-6) differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct. Additionally, groups 1 and 2 are distinct since the nucleic acids encode distinct TCR genes. For example SEQ ID NO: 1 encodes a CDR3 region derived from a VB14 TCR, while SEQ ID NO: 2 encodes a CDR3 region derived from a VB16 TCR. These are structurally distinct due to their unique sequences. Likewise, peptides derived from a BV14 or BV16 TCR (groups 3 and 4, respectively) are distinct, as are antibodies which bind said BV14 or BV16 peptides.

3. Groups 7-18 are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods comprising different method steps, different reagents, resulting in different endpoints. For example, the detection method of groups 7-12 require distinct method steps, reagents, and endpoints than the treatment methods of groups 13-18. Furthermore, the method of detection of groups 7-8 differs from the method of detection of groups 9-12, since the method of groups 7-8 requires a control subject while the methods of groups 9-12 do not. Additionally, the methods of groups 9-10, and 17-18 require a nucleic acid, the methods of groups 11-12 and 15-16 require an antibody, and the methods of groups 13-14 require a peptide. Furthermore, groups 7, 9, 11, 13, 15, and 18 require distinct reagents (i.e. a TCR VB14 peptide, nucleic acid, or specific antibody), than the methods of groups 8, 10, 12, 14, 16, and 17 (which require a TCR VB16 peptide, nucleic acid or specific antibody).

4. Groups 1-2 and 7-8, 11-16 are unrelated because the product of groups 1-2 is not used or otherwise involved in the process of groups 7-8, 11-16.

5. Groups 3-4 and 7-12, 15-18 are unrelated because the product of groups 3-4 is not used or otherwise involved in the process of groups 7-12, 15-18.

6. Groups 5-6 and 7-10, 13-14, 17-18 are unrelated because the product of groups 5-6 is not used or otherwise involved in the process of groups 7-10, 13-14, 17-18.

Art Unit: 1644

7. Groups 1-2 and 9-10, 17-18 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product, the nucleic acid encoding the CDR3 region of a TCR, could be used to isolate and clone the complete TCR gene from T cells.

8. Groups 3-4 and 13-14 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product, the TCR peptides, could be used to generate antibodies.

9. Groups 5-6 and 11-12, 15-16 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product, the antibodies, could be used to generate anti-idiotypic antibodies.

10. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by their recognized divergent subject matter. Further, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

Species Election

11. This application contains inventions drawn to patentably distinct species. Applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

Art Unit: 1644

12. Applicant is required to:

Elect a specific peptide from the group consisting of SEQ ID NO. 3, 4, or 5, SLS, SQD, and SLL, as appropriate (if groups 3-4 or 13-14 are elected).

Elect an antibody specific for a peptide from the group consisting of SEQ ID NO. 3, 4, or 5, SLS, SQD, and SLL, as appropriate (if groups 5-6, 11-12, or 15-16 are elected).

Elect a specific route of administration from the group consisting of subcutaneously, intradermal, intravenously, orally, to the muscle tissue, or to the spinal fluid (if groups 17 or 18 are elected).

And to indicate which claims read on the elected species, including any claims subsequently added.

The species of peptides are distinct because their physiochemical properties differ, due to their unique sequences. Likewise antibodies to said peptides are also distinct. Furthermore, the routes of administration are distinct since they represent distinct anatomical locations, which will target expression to different tissues. For example, administration to the spinal fluid will target the central nervous system, while oral administration will target the gut.

13. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement.

14. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

15. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the

Art Unit: 1644

inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

16. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

18. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is

Art Unit: 1644

advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Amy E. Juedes whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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February 22, 2006


3/1/06
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER